

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
PAUL FENSTER  
FENSTER & COMPANY, INTELLECTUAL PROPERTY LTD.  
P.O.BOX 10256  
PETACH TIKVA, ISRAEL 49002

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 445/05149		Date of mailing (day/month/year) <b>11 DEC 2006</b>
<b>FOR FURTHER ACTION</b> See paragraph 2 below		
International application No. PCT/IL06/00346	International filing date (day/month/year) 16 March 2006 (16.03.2006)	Priority date (day/month/year) 17 March 2005 (17.03.2005)
International Patent Classification (IPC) or both national classification and IPC IPC: A61F 2/00( 2006.01) USPC: 600/29		
Applicant CONTIPI LTD.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☒ Box No. VII      Certain defects in the international application
- ☒ Box No. VIII      Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 13 October 2006 (13.10.2006)	Authorized officer Charles Marmor II <i>Janice Paul for</i> Telephone No. (571) 272 3700
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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Inventive step (IS)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Industrial applicability (IA)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

2. Citations and explanations:

Please See Continuation Sheet

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**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**Claims 84 and 88** are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:

In line 2 of claim 84, - - said - - should be inserted before "ring".

The recitation "removal/activator device", in line 2 of claim 88, should read - - removal or activator device - -.

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-22, 63 and 83-84 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1, 63 and 83 are indefinite for the following reason(s):

The recitation "said insert selectively provides at least support to said support section", in line 6 of claim 1, is unclear because a section is not a structure by itself and therefore the "support section" may be a part of the "insert".

The recitation "said second material is more rigid than the support section" in line 1 of claim 63 is unclear because a section is a portion of an apparatus and not a structure in itself, therefore the section of an apparatus may include the second material.

The recitation of an "inner section" and "outer section", in lines 2 and 3 of claim 83, in which the inner section is capable of insertion into the outer section is unclear as a section is not a structure and therefore a single structure may comprise an inner and an outer section.

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

**V.1. Reasoned Statements:**

The opinion as to Novelty was positive (Yes) with respect to claims 5, 12, 15, 18, 34-48, 55-58, 63, 65, 68-69, 73, 82, 89-90  
The opinion as to Novelty was negative (No) with respect to claims 1-4, 6-11, 13-14, 16-17, 19-33, 49-54, 59-62, 64, 66-67, 70-72, 74-81, 83-88  
The opinion as to Inventive Step was positive (Yes) with respect to claims 5, 12, 15, 18, 34-48, 55-58, 63, 65, 68-69, 73, 82, 89-90  
The opinion as to Inventive Step was negative (NO) with respect to claims 1-4, 6-11, 13-14, 16-17, 19-33, 49-54, 59-62, 64, 66-67, 70-72, 74-81, 83-88  
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-90  
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

**V. 2. Citations and Explanations:**

Claims 1-4, 7-8, 11, 19, 21-23, 25, 27-28, 31-33 and 51 lack novelty under PCT Article 33(2) as being anticipated by McLaughlin et al. (US 5483976).

McLaughlin et al. teaches an apparatus (10, 110, 210) for treating urinary incontinence, comprising:  
a support section (2, 102, 202) that is flexible and is adapted for providing urethral support;  
an anchoring section (6, 106, 206) for resisting movement of said apparatus (as described in lines 50-57 of column 4);  
an insert (12, 112, 212), a portion of which is adapted to be positioned proximal to said support section (2, 102, 202);  
a cover (4, 104, 204) that substantially encapsulates said apparatus (as seen in Figures 1A-3B) which also expands in response to movement by the insert (12, 112, 212) and therefore can be considered part of the support section;  
a removal device (16) that changes the apparatus from a first stable position wherein the device is insertable and removable, to a second stable position wherein the device provides support to the urethra (as described in lines 5-9 and lines 42-47 of column 5);  
wherein said apparatus (10, 110, 210) is flexible (as described in lines 12-15 of column 5) (as seen in Figures 1B, 2B and 3B);  
wherein said insert (12, 112, 212) selectively provides at least support to said support section (2, 102, 202) of said apparatus (10, 110, 210);  
wherein said insert (12, 112, 212) is adapted to provide pressure to said support section causing expansion of said support section (2, 102, 202) which is cylindrical and thus expands radially (as seen in Figures 1B, 2B, 3B, 5A and 5B) (as described in lines 10-14 of column 7);  
wherein a portion of said insert (212) is elastic whereby the deformation of the elastic portion provides pressure to expand said support section (202) (as seen in the alternative embodiment in Figure 3B);  
wherein said support section (2, 102, 202) is comprised of at least one support arm (2, 102, 202) shaped like a tube;  
wherein said insert (212) is comprised of at least a supporting protrusion (215) and a locking protrusion (218) (as seen in the alternative embodiment in Figures 3A and 3B); and  
wherein said apparatus (10, 110, 210) is inserted so that pressure is applied internally to provide mid-urethral support.

Claims 1-4, 6-10, 13-14, 16-17, 19-33, 49-50 and 61-62 lack novelty under PCT Article 33(2) as being anticipated by Moser (US 6558370 B2).

Moser teaches an apparatus for treating urinary incontinence comprising:

a support section (W<sub>1</sub>) adapted to render mid-urethral support (as described in lines 49-61 of column 9) which is cylindrical

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In case the space in any of the preceding boxes is not sufficient.

and is considered to be a support arm;  
an anchoring section (opposite end to support section) which inherently resists movement of said apparatus;  
a removal device (84) (as described in lines 3-6 of column 9);  
a cover (70) that substantially encapsulates said apparatus (as described in lines 14-19 of column 7);  
wherein the entire device is inserted and is therefore considered to be an insert (72) comprising a first material (54) which exhibits first material properties and at least a second material (52) making up a tensile element or resilient support member, wherein the second material exhibits second material properties including elasticity and flexibility, wherein the insert selectively expands said support section (as seen in Figures 3-5) (as described in lines 50-54 and 59-64 of column 4; lines 39-45 of column 6);  
wherein the first material (54) is a fibrous material and is layered with the second material (52), the combination of which is elastic and flexible in order to provide comfort and support during movement of the user (as described in lines 50-64 of column 4);  
wherein the second material (52) can also be considered to be an insert (72) that is positioned proximal to and provides support to said support section (W1);  
wherein said support section (W1) is flared and wherein the general shape of the entire device is conical (as seen in Figures 1, 4 and 8);  
wherein the two materials of the insert (72) are different sizes and are rolled or folded together such that they are considered to be geometrically interlocking elements (as described in lines 33-44 of column 5 and lines 10-38 of column 6) (as seen in Figures 3-11);  
and  
wherein the second material (52) or resilient support member biases the support section away from a central axis (Y) of said apparatus;  
wherein the layers of said insert are a plurality of components removably fitted together.

**Claims 51-54, 59-60 and 64** lack novelty under PCT Article 33(2) as being anticipated by Johnson (US 4212301).  
Johnson teaches an apparatus capable of being used to treat urinary incontinence, comprising:  
a central node (16) that is a rolled sheet or flexible membrane (as seen in Figures 1 and 2) and is considered a bi-stable component as it provides structures to prevent movement in an x and y direction; and  
a plurality of protrusions for both support and for anchoring, located on said node (16) (as seen in Figures 19-21) (as described in lines 24-36 of column 2);  
a removal device or pull-string (as seen in Figures 19-21) attached to said bi-stable component for changing the apparatus from a second stable position to a first stable position;  
wherein the apparatus has said first stable position wherein the apparatus is external to the user and said second stable position wherein the apparatus is internal to the user and said protrusions are expanded to render support;  
wherein the plurality of protrusions or arms is a support section.

**Claims 66-67 and 70-71** lack novelty under PCT Article 33(2) as being anticipated by Zunker (US 6478726 B1).  
Zunker teaches an apparatus capable of being used to treat urinary incontinence, comprising:  
a connector (66) (as described by an alternative embodiment in lines 62-66 of column 12); and  
a plurality of scrolling sections;  
wherein said connector is flexible as it is made of flexible material (as described in lines 55-60 of column 8);  
wherein said plurality of scrolling sections means two sections as there are two scrolled ends as well as two different scrolled materials, the two scrolled ends being on opposite sides of the connector which encases them (as seen in Figures 4-11 and 17) (as described in lines 14-31 of column 6 and in lines 16-33 of column 7).

**Claims 72, 74 and 76-77** lack novelty under PCT Article 33(2) as being anticipated by Hull (US 2002/0138035 A1).  
Hull teaches an apparatus (12) for inserting a vaginal device, comprising:  
an enclosure (14) for containing said vaginal device (18); and  
a lubricating element located externally of said enclosure (as described in paragraphs [0046], [0047] and [0057]);  
wherein said lubricating element is a layer of lubricant applied to said enclosure which is revealed when a cover to said device and therefore to said layer is removed (as described in lines 1-5 of paragraph [0058]).

**Claims 72 and 75** lack novelty under PCT Article 33(2) as being anticipated by Arnould (US 2003/0149392 A1).  
Arnould teaches an apparatus (1) for inserting a vaginal device (6), comprising:  
an enclosure (2) for containing said vaginal device (6);  
a lubricating element (12) located externally of said enclosure (2);  
wherein said lubricating element (12) is a movable sleeve (12) located around a circumference of said enclosure (2) (as seen in Figures 1-4) (as described in paragraphs [0016] and [0038]).

**Claims 78-81** lack novelty under PCT Article 33(2) as being anticipated by LeMay et al. (US 2004/0199100 A1).  
LeMay et al. teaches an apparatus capable of extending the shelf life of a vaginal insertable device, comprising:  
an enclosure (14) adapted for receipt of at least a first portion (16) of said device and vaginal insertion;  
a section (22) adapted for receipt of at least a second portion (12) of said device such that said second portion (12) is at least partially expanded;  
wherein said section (22) is a flared enclosure that is narrower at one end than the other (as seen in Figures 1 and 2).

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In case the space in any of the preceding boxes is not sufficient.

wherein said section (22) is provided with a plurality of slots (34) between petals (30), the slots being sized and numbered to accommodate said second portion (12) of said device (as described in lines 51-58 of column 2) (as seen in Figures 2 and 5).

Claims 83-88 lack novelty under PCT Article 33(2) as being anticipated by Sanders (US 4726805).

Sanders teaches an apparatus for motivating a vaginally insertable device, comprising:  
an outer section (26, 126) or plunger, adapted for insertion into an applicator or enclosure (110);  
an inner section (140, 150) or insert, capable of coaxial insertion into and movement within said outer section (26, 126);  
a ring (134a), wherein said ring (134a) is located on said outer section (26, 126) such that friction is created by the ring (134a) when there is movement of said apparatus relative to said applicator (110) (as described in lines 32-33 and 45-47 of column 5, lines 63-68 of column 6, and line 1 of column 7);  
wherein said outer section (26, 126) or plunger is substantially located within said applicator (110) or enclosure during storage (as seen in Figures 1-4 and 9) (as described in lines 47-49 of column 5); and  
wherein said insert is attached to a removal device (42, 142) (as described in lines 17-24 of column 9).

Claim 5 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said insert is an o-ring.

Claim 12 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said insert is an invertible membrane.

Claim 15 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said insert is a resilient support member that biases at least said support section towards a central axis of said apparatus.

Claim 18 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said support section and anchoring section are comprised of at least 2 arms with a folding section.

Claims 34-40 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, at least one expander node provided with at least one expander connected to said apparatus, an elastic member that passes through said at least one expander node and a removable safety catch provided to an expanded end of said elastic member which prevents expanded end from passing through said at least one expander node, wherein said elastic member is substantially unstretched.

Claims 41-48 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising a support section, an anchoring section, a first groove, and an elastomeric ring positioned on an exterior surface of said apparatus within said first groove, wherein said elastomeric ring provides compression forces to at least a portion of said apparatus.

Claims 55-58 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a support section having a plurality of support arms, a removal device, and a bi-stable component that is a locking element or a ring slidable on an exterior of said apparatus from a first groove to a second groove; wherein the apparatus is movable from a first stable position associated with said first groove to a second stable position associated with said second groove.

Claim 63 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a support section and an insert comprising a first material which exhibits first material properties and at least a second material which exhibits second material properties, wherein said insert expands said support section and wherein said second material is more rigid than the support section.

Claim 65 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a central node that is a rolled sheet, a plurality of support protrusions located on said node and a plurality of anchor protrusions also located on said node wherein said central node has a larger diameter on one end than the other end when rolled.

Claims 68 and 69 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for



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treating urinary incontinence comprising a connector and a plurality of scrolling sections wherein said scrolling sections are provided with a plurality of protrusions for rendering urethral support or anchoring.

Claim 73 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for inserting a vaginal device comprising an enclosure and a lubricating element located externally of said enclosure, wherein said lubricating element is a ring located around a circumference of said enclosure.

Claim 82 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus comprising an enclosure adapted for receipt of at least a first portion of a vaginally insertable device and vaginal insertion, and a section adapted for receipt of at least a second portion of said device such that said second portion is at least partially expanded, wherein the apparatus further comprises a slidable sleeve located externally of said enclosure for repositioning said second portion of said device prior to insertion of said device into a user.

Claims 89 and 90 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a collapsible apparatus for inserting a vaginal device comprising an enclosure and a plunger adapted to coaxially first within said enclosure, an insert provided to said vaginal device, wherein said insert is attached to a removal/activator device; wherein said removal/activator device is removably latched to the plunger and wherein movement of the plunger out of the enclosure moves said insert at least partially through the vaginal device.

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments ?

**Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**